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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,447	08/17/2006	Osamu Tajima	049441-0144	2302

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EXAMINER	
CHEN, CATHERYNE	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,447	TAJIMA ET AL.	
	Examiner	Art Unit	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27,28 and 31-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-28, 31-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendments filed on Nov. 29, 2007 has been received and entered. Currently, Claims 27-28, 31-45 are pending. Claims 27-28, 31-45 are examined on the merits. Claims 1-26, 29-30 are canceled.

Election/Restrictions

Applicant's election without traverse of group II (Claims 27-28, newly added 31-45) in the reply filed on April 23, 2007 is acknowledged.

Response to Arguments

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

As stated in the previous Office action, Claims 27-28, 31-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibition of the reduction of bone mineral density, does not reasonably provide enablement for prevention of bone mineral density reduction. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art;

predictability or unpredictability in the art; and the breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are broadly drawn to a composition that is able to prevent bone mineral density reduction. In order to be enabled for prevention of a condition, applicant must demonstrate that the invention is able to prevent the condition each and every instance of that condition. Applicant's specification does not set forth any evidence that the claimed product is able to prevent bone mineral density reduction for all potential causes of bone mineral density reduction. In addition, the art teaches bone mineral density reduction prevention is not accepted as possible because many risk factors such as diet, age, race and family history cannot be controlled (see http://diglib.tums.ac.ir/pub/magmng/pdf/2417.pdf). Because applicant's specification does not show prevention of bone mineral density reduction and the art acknowledges that prevention is not currently possible, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if applicant's invention actually functions as claimed. Therefore, the claims are not considered enabled for the prevention of bone mineral density reduction.

Furthermore, Applicant's claim that the Applicant has shown that the claimed methodology can be preventative in every instance to reduce bone mineral density is not found persuasive because factors other than hormones are also involved in determining osteoporosis. The Pajouhi et al. conclusion is misconstrued because it only shows policy of prevention, not that prevention was actually achieved. The data from Figure 4 showing test 4 did not show significant

improvement in bone mineral density when compared to water. After standards of deviations are considered, there is not even a one fold change in bone density.

Applicant's arguments with respect to claims 27 and 28 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-28, 34-37, 41-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Bourges-Sevenier et al. (WO 02/085393 A1 with US 2005/0019438 A1 as translation).

Bourges-Sevenier et al. teaches extracts from hop, where xanthohumol, isoxanthohumol (Claim 1) at 0.01 to 50 g of isoxanthohumol (Claim 4) for treatment of hormones related to menopause, which includes osteoporosis (paragraph 0009), where the extract can be use in dietary compositions, in the form of drinks, in food supplements (paragraph 0012).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 27-28, 31-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bourges-Sevenier et al. (WO 02/085393 A1 with US 2005/0019438 A1 as translation) and Erdelmeier et al. (WO 03/014287 A1 with US 2005/0042318 A1 as translation).

Bourges-Sevenier et al. teaches extracts from hop, where xanthohumol, isoxanthohumol (Claim 1) at 0.01 to 50 g of isoxanthohumol (Claim 4) for treatment of hormones related to menopause, which includes osteoporosis (paragraph 0009), where the extract can be use in dietary compositions, in the form of drinks, in food supplements (paragraph 0012). However, it does not teach ethanol extraction, heating in alkaline water under reflux, tea, milk, yoghurt, the specific amounts per day and per time.

Erdelmeier et al. teaches extracts from hop as treatment for osteoporosis (paragraph 0004), where xanthohumol is extracted with ethanol (paragraph 0010), polar solvents, preferably hot water (paragraph 0012), alkane or

supercritical carbon dioxide, subsequent extraction using water and alcohols (paragraph 0018).

The references teach using a dosage of 0.003 to 0.5 mg/kg-weight, 0.01 to 100 mg/kg-body weight adult. However, the references do not specifically teach using all of the specific dosages claimed by applicant. The amount of a specific dosage in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The reference teaches that the dosage and administration can be varied. Thus, the reference has recognized these parameters as variables. It would have been customary for an artisan of ordinary skill to determine the optimal dosage in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of dosage amount would have been obvious at the time of applicant's invention.

Beverages as an acceptable form of drug delivery systems. Thus, an artisan of ordinary skill would reasonably expect that all types of beverages can be used to deliver the ingredients as taught by the references. This reasonable expectation of success would motivate the artisan to use tea, milk, yoghurt as drinks in the reference composition. Thus, using tea, milk, yoghurt are considered an obvious modification of the references.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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